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TITLE: Formulations and methods for reducing skin irritation

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## INVENTOR-INFORMATION:

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## CLAIMS:

What is claimed is:

1. A composition for topical application to an animal subject comprising a topical vehicle;

an irritant ingredient contained in an amount capable of inducing skin irritation in said subject; and

an anti-irritant amount of at least about 50 mM of aqueous-soluble divalent strontium cation.

2. The composition of claim 1 comprising aqueous-soluble strontium cation in a concentration of from about 50 mM to about 2000 mM.

3. The composition of claim 1 comprising aqueous-soluble strontium cation in a concentration of from about 100 mM to about 1000 mM.

4. The composition of claim 1 comprising aqueous-soluble strontium cation in a concentration of from about 250 mM to about 500 mM.

5. The composition of claim 1 comprising an amount of aqueous-soluble strontium cation capable of inhibiting mean cumulative skin irritation attributable to said irritant ingredient in a susceptible human population by at least about 20%.

6. The composition of claim 5 wherein said inhibition of skin irritation represents an average reduction in one or more of sting, burn and itch in a susceptible human population upon topical application of said composition, as compared to the level of irritation induced in said population upon topical application of a control formulation containing said irritant ingredient in a vehicle without said strontium cation.

7. The composition of claim 1 comprising an amount of aqueous-soluble strontium cation capable of inhibiting by at least about 40% the cumulative skin irritation attributable to said irritant ingredient in at least 10% of the susceptible human population.

8. The composition of claim 7 wherein said inhibition of skin irritation represents an average reduction in one or more of sting, burn and itch in at least

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10% of the susceptible human population upon topical application of said composition, as compared to the level of irritation induced in said at least 10% of the population upon topical application of a control formulation containing said irritant ingredient in a vehicle without said strontium cation.

9. The composition of claim 1 wherein said composition is a cosmetic product.

10. The composition of claim 9 wherein said composition comprises a skin exfoliant, skin peel or skin cell renewal agent.

11. The composition of claim 9 wherein said irritant ingredient comprises one or more members selected from the group consisting of carboxylic acids, keto acids, .alpha.-hydroxy acids, .beta.-hydroxy acids, retinoids, peroxides, and organic alcohols.

12. The composition of claim 11 wherein said irritant ingredient comprises lactic acid or a salt thereof.

13. The composition of claim 11 wherein said irritant ingredient comprises glycolic acid or a salt thereof.

14. The composition of claim 11 wherein said irritant ingredient comprises salicylic acid or a salt thereof.

15. The composition of claim 11 wherein said irritant ingredient comprises a combination of lactic acid and salicylic acid, or salts thereof.

16. The composition of claim 11 wherein said irritant ingredient comprises capryloyl salicylic acid or a salt thereof.

17. The composition of claim 11 wherein said irritant ingredient comprises citric acid or a salt thereof.

18. The composition of claim 11 wherein said irritant ingredient is a retinoid selected from tretinoin, retinol, and retinal.

19. The composition of claim 11 wherein said irritant ingredient comprises benzoyl peroxide.

20. The composition of claim 11 wherein said irritant ingredient comprises acetic acid or a salt thereof.

21. The composition of claim 11 wherein said irritant ingredient comprises one or more of the group consisting of 1-pyrrolidone-5-carboxylic acid, capryloyl salicylic acid, .alpha.-hydroxy decanoic acid, .alpha.-hydroxy octanoic acid, gluconolactone, methoxypropyl gluconamide, oxalic acid, malic acid, tartaric acid, mandelic acid, benzylic acid, gluconic acid, pyruvic acid and phenol.

22. The composition of claim 11 wherein said irritant ingredient comprises trichloroacetic acid or a salt thereof.

23. The composition of claim 11 wherein the pH of the composition is in the range of 1 to 6.

24. The composition of claim 11 wherein the pH of the composition is in the range of 3 to 5.

25. The composition of claim 11 having a concentration of said irritant ingredient of from about 0.1% to about 50%.

26. The composition of claim 11 having a concentration of said irritant ingredient of from about 0.5% to about 20%.

27. The composition of claim 1 wherein said composition is an antiperspirant or deodorant product.

28. The composition of claim 1 wherein said composition is a sunscreen, tanning or sunburn treatment product.
29. The composition of claim 1 wherein said composition is an insect repellent product.
30. The composition of claim 9 wherein said composition is a shaving or hair removal product selected from the group consisting of depilatory, bracer, cream, foam, gel and aftershave products.
31. The composition of claim 9 wherein said composition is a hair care or hair treatment product.
32. The composition of claim 31 wherein said composition is selected from the group consisting of shampoo, conditioner, colorant, dye, bleach, permanent wave and hair straightener products.
33. The composition of claim 9 wherein said composition is selected from the group consisting of cleansers, astringents, toners, rinses, serums and masks.
34. The composition of claim 9 wherein said composition is a facial cosmetic product.
35. The composition of claim 9 wherein said composition is selected from the group consisting of creams, lotions and moisturizers.
36. The composition of claim 1 wherein said composition is selected from the group consisting of soaps and detergents.
37. The composition of claim 1 wherein said composition is a topical drug product.
38. The composition of claim 37 wherein said irritant ingredient is capsaicin.
39. The composition of claim 37 wherein said composition is selected from the group consisting of antibiotic, analgesic, contraceptive, anti-acne and anti-dandruff products.
40. The composition of claim 39 wherein said irritant ingredient is benzoyl peroxide.
41. The composition of claim 1 wherein said composition is formulated as a rectal or vaginal suppository, foam, cream, gel, ointment, enema or douche.
42. The composition of claim 1 wherein said composition is formulated for administration to the mouth, throat or lip.
43. The composition of claim 42 formulated as a lozenge, mouthwash or gargle.
44. The composition of claim 1 formulated as a liquid, gel, cream, emulsion, suspension or stick.
45. The composition of claim 1 formulated with a physical applicator.
46. The composition of claim 45 wherein said physical applicator is selected from the group consisting of cloths, tissues, swabs, bandages and wet wipes.
47. The composition of claim 1 wherein said composition is formulated for ocular administration.
48. The composition of claim 1 wherein said composition is formulated for administration to the respiratory system.

49. The composition of claim 1 wherein said composition is formulated for administration to the gastrointestinal system.

50. The composition of claim 1 wherein said composition is formulated for administration to the reproductive system.

51. The composition of claim 1 further comprising, as counteranions to said aqueous-soluble strontium cation, one or more topically acceptable anion species.

52. The composition of claim 51 further comprising, as counteranions to said aqueous-soluble strontium cation, one or more anion species selected from the group consisting of nitrate, halogen, carbonate, bicarbonate, hydroxide, oxide, peroxide, nitrite, sulfide, bisulfate, persulfate, glycerophosphate, hypophosphate, borate and titanate inorganic anions, and carboxylic acid, alkoxylate, amino acid, peptide, saturated and unsaturated organic acid, and saturated and unsaturated fatty acid organic anions.

53. The composition of claim 51 wherein said one or more of said counteranions is an organic anion selected from the group consisting of citrate, oxalate, acetate, gluconate, lactate, tartrate, maleate, benzoate, propionate, salicylate, ascorbate, formate, succinate, folinate, aspartate, phthalate, oleate, palmitate, stearate, lauryl sulfate, lanolate, myristate, behenate, caseinate, cyclamate, pantothenate, polyaminopolycarboxylates, saccharin, thioglycolate, laurate, methylparaben, propylparaben, ricinoleate and sorbate organic anions.

54. The composition of claim 51 wherein said anion species includes nitrate.

55. The composition of claim 51 wherein said anion species includes a halogen selected from chloride and fluoride anions.

56. The composition of claim 1 further comprising at least one second anti-irritant agent.

57. The composition of claim 56 wherein the total amount of said aqueous-soluble strontium cation and said second agent is capable of inhibiting mean cumulative skin irritation attributable to said irritant ingredient in a susceptible human population by at least about 20%.

58. The composition of claim 56 wherein the total amount of said aqueous-soluble strontium cation and said second agent is capable of inhibiting by at least about 40% the cumulative skin irritation attributable to said irritant ingredient in at least 10% of the susceptible human population.

59. The composition of claim 56 wherein said second agent is selected from the group consisting of potassium channel mediating, regulating or blocking agents, calcium channel blocking or regulatory agents, sodium channel blocking agents, steroids, non-steroidal anti-inflammatory agents, aloe vera, chamomile, .alpha.-bisabolol, Cola nitida extract, green tea extract, tea tree oil, licorice extract, allantoin, urea, caffeine and other xanthines, and glycyrrhizic acid.

60. An anti-irritant composition for inhibiting animal skin irritation comprising an anti-irritant amount of at least about 50 mM of aqueous-soluble divalent strontium cation and a topical vehicle, said anti-irritant composition being packaged with instructions directing the topical administration of the anti-irritant composition to an area of animal skin that is subject to skin irritation, and said anti-irritant composition further being effective, substantially simultaneously with said topical administration, to prevent or reduce skin irritation in said area of animal skin.

61. The composition of claim 60 comprising aqueous-soluble strontium cation in a concentration of from about 50 mM to about 2000 mM.

62. The composition of claim 60 comprising aqueous-soluble strontium cation in a concentration of from about 100 mM to about 1000 mM.

63. The composition of claim 60 comprising aqueous-soluble strontium cation in a concentration of from about 250 mM to about 500 mM.
64. The composition of claim 60 wherein said inhibition of skin irritation represents a reduction in skin irritation attributable to a pre-existing human skin disease or skin irritation condition.
65. The composition of claim 64 wherein said skin irritation is attributable to atopic dermatitis, non-atopic dermatitis, asthma, rhinitis, conjunctivitis, eczema, psoriasis or infectious disease.
66. The composition of claim 60 wherein said skin irritation is ocular irritation.
67. The composition of claim 60 wherein said skin irritation is respiratory system irritation.
68. The composition of claim 60 wherein said skin irritation is gastrointestinal system irritation.
69. The composition of claim 60 wherein said skin irritation is reproductive system irritation.
70. The composition of claim 60 wherein said skin irritation is irritation of a mucous membrane.
71. The composition of claim 60 wherein said skin irritation is irritation of epidermal skin.
72. The composition of claim 60 wherein said skin irritation is irritation of dermal skin.
73. The composition of claim 64 wherein said skin irritation is attributable to environmental exposure to one or more of sunlight, low humidity, wind, cold temperature, or hot and humid conditions.
74. The composition of claim 64 wherein said skin irritation is attributable to exposure to an irritating chemical agent.
75. The composition of claim 74 wherein said irritating chemical agent exposure is attributable to application of a topical product.
76. The composition of claim 75 wherein said product is selected from the group consisting of antiperspirant, deodorant, sunscreen, tanning, sunburn treatment, insect repellant, exfoliant, skin peel, skin cell renewal, fragrance, shaving or hair removal, hair care or hair treatment, cleanser, astringent, toner, rinse, serum, masks, facial cosmetic, cream, lotion, moisturizer, soap, detergent, and topical drug products.
77. The composition of claim 75 wherein said composition is packaged with instructions directing administration of said composition before, with or following administration of said topical product.
78. The composition of claim 74 wherein said irritating chemical agent exposure is attributable to insect sting or bite, or to plant exposure.
79. The composition of claim 64 wherein said skin irritation is attributable to one or more of shaving, skin cleansing or bathing, sweating, and physical skin trauma.
80. The composition of claim 60 wherein said skin irritation is attributable to dry skin.
81. The composition of claim 60 comprising an amount of aqueous-soluble strontium cation capable of inhibiting said skin irritation in subjects experiencing the same by an average of at least about 20%.

82. The composition of claim 60 comprising an amount of aqueous-soluble strontium cation capable of inhibiting said skin irritation by at least about 40% in at least 10% of the subjects experiencing the same.

83. The composition of claim 60 wherein said composition is formulated as a rectal or vaginal suppository, foam, cream, gel, ointment, enema or douche.

84. The composition of claim 60 wherein said composition is formulated for administration to the mouth, throat or lip.

85. The composition of claim 84 formulated as a lozenge, mouthwash or gargle.

86. The composition of claim 60 wherein said composition is formulated for ocular administration.

87. The composition of claim 60 wherein said composition is formulated for administration to the respiratory system.

88. The composition of claim 60 wherein said composition is formulated for administration to the gastrointestinal system.

89. The composition of claim 60 wherein said composition is formulated for administration reproductive system.

90. The composition of claim 60 formulated as a liquid, gel, cream, emulsion, suspension or stick.

91. The composition of claim 60 formulated with a physical applicator.

92. The composition of claim 60 further comprising, as counteranions to said aqueous-soluble strontium cation, one or more topically acceptable anion species.

93. The composition of claim 92 further comprising, as counteranions to said aqueous-soluble strontium cation, one or more anion species selected from the group consisting of nitrate, halogen, carbonate, bicarbonate, hydroxide, oxide, peroxide, nitrite, sulfide, bisulfate, persulfate, glycerophosphate, hypophosphate, borate and titanate inorganic anions, and carboxylic acid, alkoxylate, amino acid, peptide, saturated and unsaturated organic acid, and saturated and unsaturated fatty acid organic anions.

94. The composition of claim 92 wherein said one or more of said counteranions is an organic anion selected from the group consisting of citrate, oxalate, acetate, gluconate, lactate, tartrate, maleate, benzoate, propionate, salicylate, ascorbate, formate, succinate, folinate, aspartate, phthalate, oleate, palmitate, stearate, lauryl sulfate, lanolate, myristate, behenate, caseinate, cyclamate, pantothenate, polyaminopolycarboxylates, saccharin thioglycolate, laurate, methylparaben, propylparaben, ricinoleate and sorbate organic anions.

95. The composition of claim 60 further comprising at least one second anti-irritant agent.

96. The composition of claim 95 wherein said second agent is selected from the group consisting of potassium channel mediating, regulating or blocking agents, calcium channel blocking or regulatory agents, sodium channel blocking agents, steroids, non-steroidal anti-inflammatory agents, aloe vera chamomile, .alpha.-bisabolol, Cola nitida extract, green tea extract, tea tree oil, licorice extract, allantoin, urea, caffeine and other xanthines, and glycyrrhizic acid.

97. A method for inhibiting skin irritation associated with an irritant ingredient contained in an applied topical formulation, comprising topically administering to an animal subject the composition of claim 1.

98. A method for inhibiting skin irritation in an animal subject comprising topically administering to the subject the composition of claim 60.

99. The method of claim 98 wherein said composition is administered within about three hours prior to application to the subject of a second topical formulation containing an irritant ingredient.
100. The method of claim 98 wherein said composition is administered substantially simultaneously with application to the subject of a second topical formulation containing an irritant ingredient.
101. The method of claim 98 wherein said composition is administered to inhibit skin irritation attributable to a pre-existing animal skin disease or skin irritation condition.
102. The method of claim 98 wherein said skin irritation is ocular irritation.
103. The method of claim 98 wherein said skin irritation is respiratory system irritation.
104. The method of claim 98 wherein said skin irritation is gastrointestinal system irritation.
105. The method of claim 98 wherein said skin irritation is reproductive system irritation.
106. The method of claim 98 wherein said skin irritation is irritation of a mucous membrane.
107. The method of claim 98 wherein said skin irritation is irritation of epidermal skin.
108. The method of claim 98 wherein said skin irritation is irritation of dermal skin.
109. The method of claim 101 wherein said skin irritation is attributable to environmental exposure to one or more of sunlight, low humidity, wind, cold temperature, or hot and humid conditions.
110. The method of claim 101 wherein said skin irritation is attributable to exposure to an irritating chemical agent.
111. The method of claim 101 wherein said skin irritation is attributable to one or more of shaving, skin cleansing or bathing, and physical skin trauma.
112. The anti-irritant composition of claim 60 wherein said skin irritation is characterized by one or more of sting, burn or itch.
113. The anti-irritant composition of claim 60 wherein said skin irritation is itch.